CUPID Discrete Choice Experiment Survey (INDIVIDUAL)

NOTE: This survey will be administered using a tablet computer.

Section 0: Home Screen Information (completed by research staff)
0.1 PTID: (numeric)
0.2 Re-entry of PTID for confirmation: (numeric)
0.3 Couple ID:
0.4 Mark participant's sex [pop-up box to confirm correct entry]: Male Female
0.5 Today's date [drop-down selections for DD/MTH/YR]
0.6 Staff Initials:
0.7 Interview location Study clinic Community location
0.8 Has the participant watched the MTN-045 CUPID video? Yes No

Introduction

As you just heard in the video, scientists are developing new "2 in 1" products that can prevent HIV and pregnancy at the same time (these can also be known as dual purpose prevention products). We would like to ask what product characteristics (features that define the product) are most important to you in choosing among different options for HIV and pregnancy prevention. We also would like to ask questions about you, your opinions, and your experiences.

I will now explain to you the different product characteristics.

Table of product attributes and levels that will comprise the experimental design to generate hypothetical product profiles and choice sets.

Note: This table is included for summary purposes only and will not be presented to participants; rather they will be introduced to each attribute individually, as presented in subsequent pages. Design restrictions (i.e., attribute & level combinations that will not be presented) are indicated in grey.

Attributes	Level 1		Level 2			Level 3											
Product	Oral tablet		Vaginal film or insert			Vaginal ring											
Duration	Use before sex	Daily	Weekly	Monthly	Use before sex	Daily	Weekly	Monthly	Use before sex	Daily	Weekly	Monthly					
Stomach cramps/nausea	Rare	Rarely		Frequently													
Menstrual changes	No changes to bleeding	~	No changes to	~	No changes to Bleed	-		~	es to		leeding may be eavier		Spotting or bleeding between menses		bleeding between		
How vagina feels during sex	No changes		Vagina feels wetter		Vagina feels drier												
Return to fertility	Immediately		In 3 months		In 6 months												

Note to Interviewer: Present the accompanying placebo product model to participants as each one is described.

A pill taken by mouth: One product would be tablets that you take by mouth. The medicines to prevent HIV and pregnancy are in the tablet and are released inside you after you swallow it. The tablet does not have to be taken with food.



A ring inserted in the vagina: One product is a ring inserted in the vagina. The medicines to prevent HIV and pregnancy are inside the ring and are slowly released inside of you over time. When you receive the ring you would be shown how to insert and remove it yourself. After it is inserted, most women do not feel it at all. Most male partners do not feel it during sex.



A product inserted into the vagina that dissolves. A product that is inserted into the vagina and dissolves could come in different forms, like a film or an insert. The film and insert contain medicines to prevent HIV and pregnancy. Both the film and the insert dissolve shortly after being placed in the vagina, and the medicines are then released.

The vaginal film is a thin, flexible material that comes in individually packaged foil wrappers. To insert the film into the vagina, you would fold it in half, place it over your fingertip, and push it as far as possible into the vagina with your finger. The insert looks like a tablet and is put in the vagina with a finger.



Injectable: This product would be an injection that contains the medicines to prevent HIV and pregnancy. The medicines cannot be removed once they are injected into your body. This product could be given as one injection or two injections in the arm or buttocks.

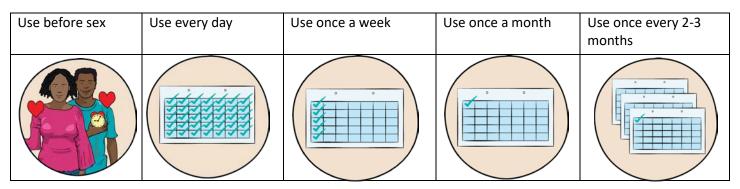


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How often you will need to use it

These products could be designed to last for different lengths of time. Some products need to be taken daily, while others stay in your body and work for longer. Some would need to be used only when you have sex while others are used on a regular schedule even if you don't have sex. It is important to use the products as instructed for them to work properly.

Here are some possible options for how often you would need to use a product:



1.	Have you ever used any kind of medicine that you had to take every day for one week or more?
	\square_1 Yes
	\bigcap_2 No \rightarrow skip to 3

2.	Was it easy	or difficult to take it every day	/?

- It was easy to take it every day
 It was not so easy to take every day (e.g., I missed one or two days)
- 3. Have you ever used any kind of medication, such as an injection, that you had to take once every month or every few months?

It was difficult to take it every day (e.g., I missed many days)

 \square_2 No \rightarrow skip to sample question to assess comprehension of use frequency (after Q4)

4. How easy or difficult was it to remember to receive the product each month?

a Easy to refill (or receive) the product every month

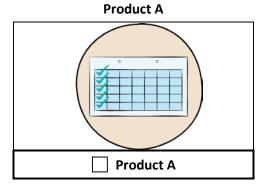
1 Not so easy to refill (or return to the clinic or pharmacy for) my product (e.g., I was a little bit late)

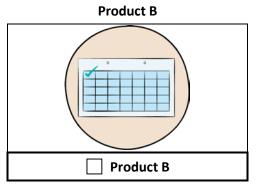
Difficult to remember to go back to receive it on time (e.g., I was very late)

I would like to make sure the pictures make sense to you.

In the following two pictures, which one shows a product that must be used more often?

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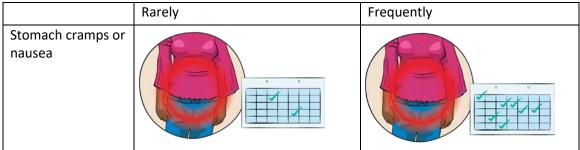
Side effects

Sometimes people who use HIV prevention or family planning products experience side effects.

Common side effects may include headaches or dizziness, while other may experience stomach cramps or nausea. For most women, these side effects happen when they start using the products and last for the first few weeks or month.

These problems usually go away after your body has adjusted to the medicine.

These side effects may happen very rarely during the first month or, for some women, they happen more frequently.



5.	Have you ever had	any of the following side-effects whe	n you have taken a medicine in the p	oast? (mark all that
	apply)			
	Nausea/upse	t stomach		
	2 Headaches/d	izziness		
	☐₃ Weight gain			
	4 Other			
	☐₅ Have not use	d a medicine in the past \rightarrow skip to nex	at section, menstrual changes	
	\square_6 None \rightarrow skip	to next section, menstrual changes		
6.	·	oped using a medicine because of side	e-effects in the past?	
	₁ Yes			

7. Which type of side effect led you to stop using a medicine? (mark all that apply)

	<i>,</i> ,
1	Nausea/upset stomach

Headaches/dizziness

☐₃ Weight gain

______ Other (specify):_____

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 \square_2 No \rightarrow skip to next section, menstrual changes

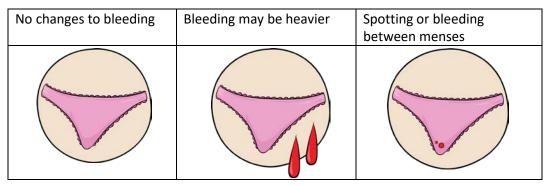
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Menstrual changes

Some products that are used for family planning can cause changes to a woman's menstrual cycle, and this could also be true for a "2-in-1" product that would have family planning medicine in it. Some products may make the cycle irregular (like having periods more frequently or less frequently than usual), some could cause light spotting or bleeding between menses/periods, while others may make bleeding heavier. Some will cause no changes. Some women find menstrual changes acceptable while others worry about not having a regular cycle.

Any changes to bleeding will not influence a woman's overall health.

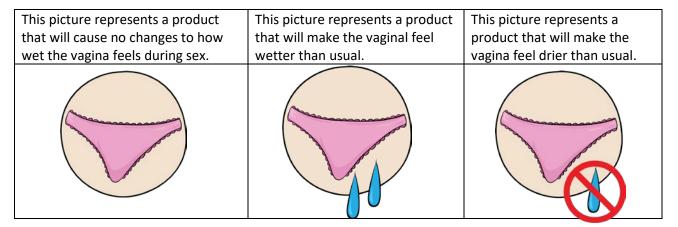
These pictures represent the following:



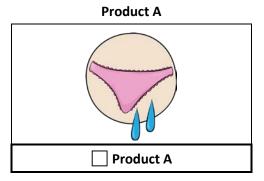
8.	Have you (<i>male</i> : Has your partner) ever used a family planning product that changed your (<i>male</i> : her) menstrual cycle? \square_1 Yes \square_2 No \rightarrow skip to 11 \square_3 Don't know \rightarrow skip to 11
9.	How was the menstrual cycle changed? (mark all that apply) 1 The product made the bleeding heavier 2 The product caused spotting or bleeding between menses 3 4 Other
10.	Have you (<i>male</i> : Has your partner) ever stopped using a type of family planning product because of the changes to your (her) menstrual cycle? \Box_1 Yes \Box_2 No
11.	In the last year have you felt that your (<i>male</i> : partner's) menstrual cycle interfered with your sexual relationship? \square_1 Yes \square_2 No

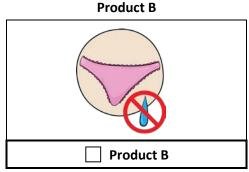
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Some dual purpose prevention products may change how the vagina feels when you are having sex, which may affect your pleasure or how sex feels, while others may not. The changes may make the vagina feel wetter or drier than usual. These changes should not make sex uncomfortable or cause irritation.



HOW VAGINA FEELS DURING SEX Check-Up: In the following two pictures, which one shows a product that may make the vagina feel wetter during sex?

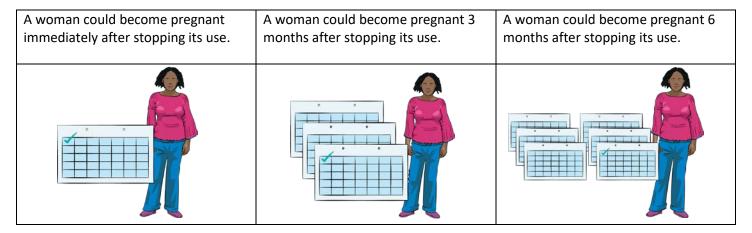




Return to fertility

Some dual purpose prevention products, because of the medicines in them to prevent pregnancy, may affect how quickly you are able to become pregnant after you stop taking them. With some, a woman's ability to get pregnant will continue on the regular cycle or start again immediately after stopping use of the product. With others, it may take some months before the woman is able to get pregnant again. No product will cause a woman to become infertile.

These pictures represent a product where...



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Discrete Choice Questions

Now we will ask you to make choices between two imaginary dual purpose prevention products. Consider the different advantages and disadvantages for each of the two products, and then select which product you would prefer to use yourself (*male*: you would prefer for your partner).

When you make your choice, review each characteristic of the product described then choose whether you prefer Product A or Product B.

In making your choices, we would like you to think about the questions as though you want to prevent pregnancy and HIV, even though you may not currently be using HIV or pregnancy prevention methods with the partner who joined this study with you.

After each choice, I am going to ask you to think about the product you selected, and whether you would rather (*male*: have your partner) use that product, use a male condom, or neither.



If used properly, male condoms are a "two-in-one" product that protect you from both HIV and pregnancy.

Instruction to interviewer: For participants who are unfamiliar with condoms ONLY, offer the following description:

Male condoms are worn on the penis of the male sex partner. For condoms to protect you from HIV, your partner has to use one <u>every time</u> you have sex together.

They do not have any side-effects, and using them will cause no changes in menstruation.

I am now going to ask you to make your choices between two possible products.

Please review the characteristics of each one and make your choice between Product A and Product B.

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Product A	Product B
Oral tablet	Vaginal film
Use once a week	Use once a month
Rarely	Frequently
Hulciy	rrequently
No changes to bleeding	Spotting or bleeding between menses
Vagina feels wetter	Vagina feels drier
Immediately	In 3 months

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	se Product [A or B]. If Product [A or B] was available to you, what would you use now? 1 Use the product I chose 2 Female: Have my partner use a condom/Male: Use a male condom
_	3 Use neither
	Note: Participants will be randomized to respond to approximately 8 choice questions derived based on an experimental design.

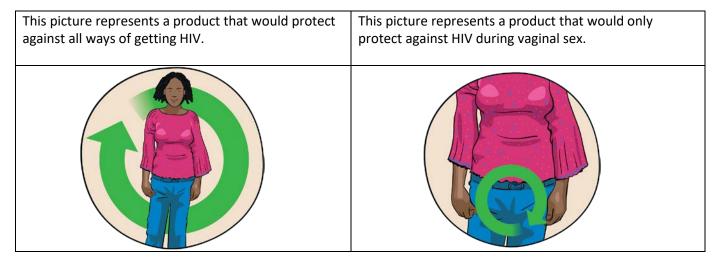
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Type of HIV Protection

Because dual purpose prevention products may work in different ways, some provide protection from all ways someone could be infected by HIV. This includes different types of sex, like vaginal and anal sex, as well as by other ways people can get HIV, such as sharing of needles for drug use or other reasons. Other products would provide protection from HIV for vaginal sex only but would not protect against other ways people can get HIV.

For some people, they may think it is important to protect against HIV from all ways of getting infected; whereas for others, their main concern for HIV protection is during vaginal sex. Using a product that protects against all ways people can get HIV usually means there is more medicine in your body.



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1. If you were selecting a dual purpose product to use for HIV and pregnancy prevention right now, how important would each of the following things be to you in making your choice?

	Very Important (1)	Somewhat important (2)	Not important (3)
How the product is taken (swallowed by mouth, inserted in the vagina, injected) (1)	0	0	0
How soon you/your partner can get pregnant after using it (2)	0	0	0
Whether it changes menses (3)	0	0	0
Whether it causes the vaginal to feel wetter during sex (instead of not changing the vagina) (4)	0	0	0
How often it has to be used (daily, monthly) (5)	0	0	\circ
Whether it causes nausea (6)	0	0	0
Whether it protects against all ways of becoming HIV infected (instead of protection during vaginal sex only) (7)	0	0	0
Whether it protects against other sexually transmitted infections, such as herpes or chlamydia (8).	0	0	

2. Which one of these characteristics is the MOST important to you now, if you were selecting a dual prevention product?

[Response choices will be drawn from answers to #1]

3. Of the characteristics you selected as being NOT important, which one is the LEAST important for you now?

[Response choices will be drawn from answers to #1]

4. Please rank the five products we have shown you today in order of your preference for using them as a "2 in 1" method to prevent both pregnancy and HIV prevention.
(Present show card A: If participant has trouble ranking, ask them to point to the products in order of the one they like the best to the one they like the least.) Oral tablets Vaginal ring Vaginal film Vaginal insert Injections
5. Of the five products, which ones would you <u>definitely not</u> consider using (<i>male</i> : having your partner use) as a "2 in 1" method in the future? You can select more than one. Oral tablets Vaginal ring Vaginal film Vaginal insert Injections None selected
6. Asked if Injections not selected in 5:
I would like to ask you more about the injections. Consider that with injections, the HIV medicine in the injection stays in the body for 12 months (1 year) after the last injection. The amount of medicine that stays in the body is too little to protect one from HIV, but is enough to put one at risk of getting resistant HIV. (Resistant HIV is HIV infection that's harder to treat). Someone using the injection would need to take oral HIV PrEP pills daily for up to 1 year after stopping the injection to protect against HIV. This is important until the HIV medicine from the injection is completely gone from the body. We are interested to know whether this affects your opinion about the injection.
 6a. Would you consider using the injection [male: having your partner use the injection] if you/she also needed to take daily oral PrEP tablets for 1 year after stopping use of the injection? Yes No Unsure
6b. Thinking about the injection now requiring oral PrEP pills daily for one 1 year after stopping the injection, please rank the five products in order of your preference for using them as a "2 in 1" method to prevent both pregnancy and HIV prevention.
(Present show card B: If participant has trouble ranking, ask them to point to the products in order of the one they like the best to the one they like the least.) Oral tablets Vaginal ring Vaginal film Vaginal insert Injections with oral PrEP for 1 year

 $MTN-045 \ (CUPID): English \ DCE \ Question naire$

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7. Would you prefer using a 2-in-1 product that is taken on a regular schedule - that is, daily, weekly, monthly - or a product used only when you have sex? Regular schedule Only when I have sex
8. For each of the products, what would be the ideal frequency for how often they needed to be used or taken? 8a. Oral tablets Every day Once a week Once a month 8b. Vaginal product that dissolves At the time you have sex (used before sex) Once a week Every two weeks
8c. Vaginal ring Monthly Every 2 months Every 3 months 9. My last question is about the products is about oral tablets. I would like your opinion on whether you prefer the medicines for HIV and pregnancy prevention to be in a single tablet vs. separately in two tablets that you would take at the same time.
 This image show two pills—one for HIV prevention and one for pregnancy prevention—that are packaged together, but as separate pills. Using two separate pills packaged together is the simplest and easiest way for drug manufacturers to provide a daily product to prevent both HIV and pregnancy without changing the medication itself. The packaging is meant to help someone remember if they have taken their pill(s) daily or not. The second image shows just a single tablet for both purposes. Just the single tablet would need to be taken to prevent both HIV and pregnancy.
Would you prefer a tablet a single tablet that combines both HIV and pregnancy prevention or 2 tablets (one for HIV and one for pregnancy prevention) that are packaged together?
☐ Single tablet ☐ 2 tablets packaged together ☐ No preference

INSTRUCTIONS:

- Complete the behavioral and demographic questionnaire.
- Explain to participant that this they have finished with this part of the interview and will now rejoin their partner to complete the second part of the visit.

Thank you for taking time to participate in the study today and to provide your opinions about potential new 2-in-1 products to prevent HIV and pregnancy.

Select language(s) used for the survey:		
Luganda		
Shona		
English		

Introduction

Members of the couple come back together

CUPID Discrete Choice Experiment Survey (COUPLES)

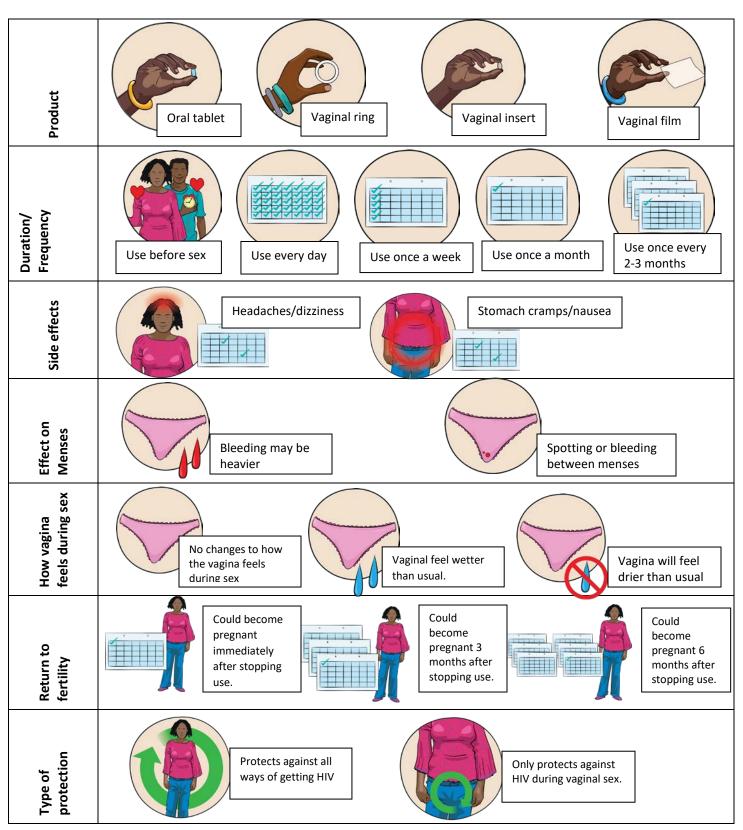
- Explain that they will do a similar activity to the one they just did by themselves, but this time it will be with their partner
- Ask them to talk aloud as they go through the choice sets, explain that we are interested in hearing how they are making decisions and what each of them thinks.
- Conduct DCE with couple, then move to "ideal product" activity.

Interviewer will complete the Couples Observation Checklist to document couples' interactions and decision-making.

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Ideal product activity: If you could choose between all the options we have talked about to create your "ideal 2-in-1" product, what would it look like? You can think about this as a couple. For each row below, circle one thing to create your "ideal" product.



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1.	if the product you just created was available to you today, would you use it?
	Yes No
2.	Would you prefer to use the product you just created or a male condom?
	Product created Male condom

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